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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/539,777

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EXAMINER

SU, SUSAN SHAN

ART UNIT

PAPER NUMBER

4193

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/539,777	Applicant(s) TANGHOEJ, ALLAN	
	Examiner SUSAN SU	Art Unit 4193	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☒ Claim(s) 18 and 19 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 June 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8 & 15 February 2006</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Specification

2. The abstract of the disclosure does not commence on a separate sheet in accordance with 37 CFR 1.52(b)(4). A new abstract of the disclosure is required and must be presented on a separate sheet, apart from any other text.
3. The spacing of the lines of the abstract is such as to make reading difficult. New application papers with lines 1½ or double spaced on good quality paper are required.

Drawings

4. The drawings are objected to under 37 CFR 1.83(a) because they fail to show “the periphery 10 of the oblong member” as described in on page 14, line 30 of the specification. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are

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not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

5. Claims 1-19 are objected to because of the following informalities:

For claims 1, 5, & 15: the word "bend" is misspelled; it should be changed to --bent--;

For claim 10: it is dependent on the non-preceding claim 11; the examiner believes that claim 10 is dependent on claim 9 and has carried out the examination of this instant claim under that assumption;

For claim 10: the statement is grammatically incorrect; "is" should be changed to --are--. Appropriate correction is required.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-5, 8, 13, & 15-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Bolmsjö (WO 02/36192).

With regard to claim 1, figure 2 of Bolmsjö teaches a device for opening a human bladder comprising an oblong member for opening the urethral sphincter (page 13 lines 18-20 where "the point of closing or the obstruction of the urethra" is interpreted to be the urethral sphincter), said oblong member (#10) comprising means for draining fluid from the bladder (#17), and a guide member (#14) for manipulating the oblong member, wherein the guide member in a first configuration is bent (as shown by the curvature of #14) and the guide

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member allows unfolding from said first configuration into a second configuration (as shown by the straight configuration of figure 4) allowing for insertion of the oblong member in a urinary tract (as shown by figures 8-10, page 10 lines 29-31).

With regard to claim 2, Bolmsjö also teaches that the cross-sectional area of a major part of the guide member (#14) at least in said first configuration (as shown by the curvature of #14 in figure 2) is substantially smaller than the cross-sectional area of the oblong member (#10).

With regard to claim 3, Bolmsjö also teaches that in said second configuration (as shown by the straight configuration of #14 in figure 4) the cross-sectional area of a major part of the guide member (#14) is smaller than the cross-sectional area of the oblong member (#10).

With regard to claim 4, Bolmsjö also teaches that the guide member (#14) in said first configuration is rolled (as seen in the curvature of #14 in figure 2).

With regard to claim 5, Bolmsjö also teaches that at least a part of the guide member (#14) in said first configuration (as shown by the curvature of #14) is bent by an essentially elastic formation of said guide member (as seen from the lack of kinks of #14 in all figures).

With regard to claim 8, Bolmsjö also teaches that the guide member (#14) comprises gripping means (#15).

With regard to claim 13, Bolmsjö also teaches that at least part of the device is provided with a surface which is hydrophilic (page 6 line 10, where silicon or polyurethane inherently has some hydrophilic properties).

With regard to claim 15, Bolmsjö also teaches that the oblong member (#10) allows storage in a bent configuration (see figure 2).

With regard to claim 16, figure 11 of Bolmsjö also teaches a guiding device (#28, #29, & #22') with a compartment (inside #22') for guiding drained urine (#22' is left hollow and therefore capable of guiding drained urine when left at the entrance to the urinary canal), the guiding device being adapted to convey the oblong member (#10, not labeled) from the

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compartment (#29 is designed to push the oblong member away from the compartment) and into a urinary canal.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 6-7 are rejected under 35 U.S.C. 103(a) as being obvious over Bolmsjö (WO 02/36192) in view of Gambale (U.S. Patent 6,231,564).

With regard to claim 6, Bolmsjö teaches the device of claim 1 but does not teach that it is packed in said first configuration, wherein the guide member is adapted to unfold upon un-packaging of the device. However, figures 5-7 of Gambale teach a guide member (#20) packed in said first configuration wherein the guide member is adapted to unfold upon un-packaging (tab #24 keeps the package together) of the device. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Bolmsjö so that the guide member is packed in said first configuration and adapted to unfold upon un-packaging as taught by Gambale for the purpose of preventing kinks in a long guide member.

With regard to claim 7, Bolmsjö teaches the device of claim 1 but does not teach that the guide member is made of metal or from a polymer material or from a composite material. However, Gambale teaches that the guide member (#20) is made of metal (Col. 9 line 23) or from a polymer material or from a composite material. It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the material taught by Gambale in the device of Bolmsjö for the purpose of achieving the desired rigidity and flexibility required for the guide member utility.

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10. Claims 9-12, 14, & 17 rejected under 35 U.S.C. 103(a) as being obvious over Bolmsjö (WO 02/36192) in view of Tihon (U.S. Patent 5,562,622).

With regard to claim 9, Bolmsjö teaches all of claim 1 but does not teach that the device further comprises a slack tube, the slack tube being less rigid than the oblong member. Tihon teaches a device for opening a human bladder comprising a slack tube (#24 or #26, both point to the same feature, see figure 1). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Bolmsjö with a slack tube as taught by Tihon for the purpose of facilitating collection of urine (e.g. directing the flow of urine into a collection bag). It is asserted by the examiner that making the slack tube less rigid than the oblong member is an obvious case of design choice because its rigidity does not contribute to its function in urine collection.

With regard to claim 10, in the modification of claim 9, Tihon also teaches that the slack tube and the oblong member are provided in one piece (see figure 9).

With regard to claim 11, in the modification of claim 9, Tihon also teaches that the slack tube is longer than the guide member (Col. 4 lines 22-24).

With regard to claim 12, in the modification of claim 9, Tihon teaches that the slack tube comprises gripping means (Col. 6 lines 15-16, inherent in the phrase "pulling on the tube 26") but does not teach that the gripping means is used for removing the oblong member from a urinary canal. It is asserted by the examiner that while Tihon teaches said gripping means for detaching the slack tube from the oblong member, the same gripping means can function to remove the oblong member from the urinary canal as long as the user does not simultaneously employ a stabilizing push rod (#52) to hold the oblong member in place. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the gripping means as taught by Tihon for the removal of the oblong member.

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With regard to claim 14, Bolmsjö teaches all of claim 1 but does not teach that the oblong member is solid. Tihon teaches that the oblong member (#12) is solid. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Bolmsjö with Tihon for the purpose of providing an oblong member that has desirable elastic memory properties without the addition of a metal wire.

With regard to claim 17, Bolmsjö teaches the device of claim 16 but does not teach that it further comprises a receptacle in fluid communication with the compartment of the guiding device. Tihon teaches a device for opening a human bladder comprising a receptacle connected to the urine collection tube of the device (Col. 5 lines 15-18). It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate a receptacle as taught by Tihon into Bolmsjö for the purpose of allowing for easier clean-up. After the modification, the receptacle would be in fluid communication with the compartment of the guiding device because the guiding device acts as a urine collection tube (as disclosed by the applicants in claim 16).

Allowable Subject Matter

11. Claims 18-19 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

With regard to claim 18, no prior art has been found to show or suggest the device of claim 16 "further comprising sealing means to seal between the compartment and the urinary canal" in combination with the limitations of recited in the claim.

With regard to claim 19, no prior art has been found to show or suggest the device of claim 16 "wherein the receptacle is formed in a flexible material allowing manipulation of the guide member through a wall of the receptacle" combination with the limitations recited in the claim.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Rosenberg et al. (U.S. Patent 4,692,149) teaches a catheter comprising a flexible drainage shaft and a removable connector.

Burton et al. (U.S. Patent 4,909,785) teaches an apparatus for drainage that opens the urethral sphincter.

Haacke et al. (U.S. PGPub 2002/0123739) teaches a ureter drainage device with a sliding hose coupled to the urethral catheter.

Eshel et al. (U.S. PGPub 2003/0153899) teaches a catheter comprising first and second tubular members and connectors for communication with exterior receptacles.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSAN SU whose telephone number is (571)270-3848. The examiner can normally be reached on M-F 8:30AM-6:00PM EST (alternate Fridays off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long T. Nguyen can be reached on 571-272-1753. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

S. Su

/Long Nguyen/
Supervisory Patent Examiner
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